

SEP 26 2002

K020457

## 510(k) Summary of Safety and Effectiveness

In Accordance with CFR 807.92 (April 26, 1992), the following information is submitted:

1. Name: AXIAMED, Inc.  
Address: 5200 Willson Road  
Suite 150  
Edina, MN 55424

Phone: 952 836-2660  
Fax: 952 836-2661

Contact: W. Allen Putnam  
Date of Summary Preparation: July 12, 2002

2. Name of Device: AXIAMED Trans-Sacral Spinal Access Device  
Generic Name: Rigid Endoscope and Instrument Set

3. Predicate Devices:

Surgical Dynamics, Inc., 30K Working Channel Scope and instrument kit for Discectomy

Argus Medical Company Laparoscopic Discectomy Instrument System

The Nucleotome System and Probe Kits.

Surgical dynamics Discography System

Sofamor Danek USA, Inc., Micro Endo Instruments

4. Device Description:

The AXIAMED Trans-Sacral Spinal Access Device is for minimally invasive access to the anterior lower spine and consists of the following components:

Blunt Trocar with Trocar Guide Stylet  
Threaded Guide  
Dilator Sheath, Small  
Dilator Sheath, Large  
Threaded Guide Sheath, 3mm  
Threaded Guide Sheath, 4mm  
Drill Bit, 3 mm  
Drill Bit, 4mm  
Delivery Cannula with blunt stylet



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. W. Allen Putnam  
AXIAMED, Inc.  
5200 Wilson Road, Suite 150  
Edina, Minnesota 55424

Re: K020457

Trade Name: AXIAMED Trans-Sacral Spinal Access Device  
Regulation Number: 21 CFR 888.1100  
Regulation Name: Arthroscope  
Regulatory Class: II  
Product Code: HRX  
Dated: July 12, 2002  
Received: July 15, 2002

Dear Mr. Putnam:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

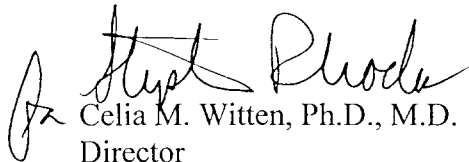
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. W. Allen Putnam

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", is written over the printed name.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and


Radiological Health

Enclosure

K020457

#### INDICATION FOR USE

The intended use of the AXIAMED Trans-Sacral Spinal Access Device is for minimally invasive access to the anterior portion of the lower spine for the purpose of assisting in the treatment of decompression of the lumbar disc or the performance of lumbar discectomy.

  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K020457